OMISSION OF RELEVANT EPIDEMIOLOGIC DATA

The EPA failed to include in its meta-analysis of United States studies relevant data from two major spousal smoking studies.[1,2] These two studies appeared in the scientific literature months prior to the release of the final Risk Assessment. Similarly, the EPA failed to consider data on workplace and childhood exposures reported in the 30 epidemiologic studies of spousal smoking.

- Funded in part by the National Cancer Institute, the 1992 Brownson, et al., study is one of the largest studies ever conducted on ETS exposure and lung cancer incidence.[1] It was not included in the Risk Assessment.

- The EPA had access to the two studies well in advance of the release of the final Risk Assessment.

- If the two studies were included in the EPA's meta-analysis of U.S. studies, a statistically nonsignificant cumulative risk estimate for spousal smoking would be calculated, even at the 90% confidence interval used by the EPA.[3]

- The inclusion of both the studies in the meta-analysis should negate the classification of ETS as a Group A carcinogen, in that a cumulative risk estimate for the U.S. studies would not be statistically significant, even at the 90% confidence

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interval.[3] The Agency should have estimated no statistically significant increased risk for lung cancer, at either a 95% or a 90% confidence interval.

- A meta-analysis including the two recent studies was forwarded to the EPA more than one month prior to the release of the final Risk Assessment.[3] The EPA chose not to include those data in its statistical calculations in the final Risk Assessment.[4]

- In relying on the 30 spousal smoking studies, the EPA selectively chose which data to use. For instance, although 11 of the 30 epidemiologic studies considered by the EPA also assessed workplace exposures to ETS, the Risk Assessment did not address those data.[5-15]

  Nine of the 11 spousal smoking studies that examined workplace exposures reported no statistically significant association with lung cancer.[5,7,8,10-15] If the data on workplace exposure reported in the 11 studies are pooled in a meta-analysis such as the one conducted in the Risk Assessment, the summary risk estimate is not statistically significant.[16]

- Similarly, ten of the 30 epidemiologic studies contained data regarding reported exposures to ETS during childhood. The Risk Assessment also failed to consider those

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data.[6,8,10,12,17-22]

Nine of the ten studies examining reported exposures to ETS during childhood reported no statistically significant association for lung cancer in adult nonsmokers.[6,10,12,17-22]

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FAILURE TO CONSIDER OTHER RELEVANT DATA

Although the Risk Assessment references data on mainstream smoke, EPA did not adequately discuss relevant scientific literature on ETS, including animal studies and studies of mutagenicity and genotoxicity.

- EPA does not adequately discuss the available data from animal studies of ETS exposure. The only animal data referred to in the Risk Assessment are from a single inhalation study on hamsters in which it was reported that animals exposed to mainstream smoke exhibited an increase in laryngeal tumors; several studies on lung implantation of tobacco smoke condensates; and several results from studies of mouse skin-painting of cigarette smoke condensates.

  Studies relating to laryngeal cancer and to the reported results from implantation or skin-painting studies have little relevance to either the expected route of exposure for ETS, i.e., inhalation to the lung, or to the disease endpoint under discussion (lung cancer).

- Animal inhalation studies employing fresh sidestream smoke and ETS were not discussed in the Risk Assessment.

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All three publicly available studies to date have reported no statistically significant increased incidence of tumors in animals exposed to ETS compared with controls.[1-4]

Moreover, the Risk Assessment fails to recognize that none of the lifetime, "whole smoke" exposure studies on animals, originally designed to assess possible biological effects from mainstream smoke exposures, have reported the induction of lung carcinomas via inhalation.

- EPA fails to discuss the results of studies comparing levels of mutagens and other genotoxic markers in the body fluids of exposed and non-exposed nonsmokers.[5-14]

  These data suggest no statistically significant increases in mutagenic activity in the body fluids of nonsmokers exposed to realistic levels of ETS compared with nonsmokers who are not exposed.

- Moreover, the "carcinogenic agents" supposedly identified in tobacco smoke (e.g., the "list" of suspected carcinogens referred to in the Risk Assessment) either are not suspected pulmonary carcinogens or have not been unequivocally demonstrated as tumorigenic in human tissue or in the lung tissue of experimental animals.[15-17]

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